PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Kenji NAKAJIMA

Docket No: Q78108

Appln. No.: 10/692,011

Group Art Unit: 1641

Confirmation No.: 8536

Examiner: Unsu Jung

Filed: October 24, 2003

For: ASSAY METHOD USING A BIOCHEMICAL ANALYSIS UNIT AND BIOCHEMICAL ANALYSIS APPARATUS

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. § 41.37, Appellant submits the following:

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I. REAL PARTY IN INTEREST

The real party in interest is FUJIFILM Corporation.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representative and the Assignee of this application are not aware of any other appeals or interferences that will directly affect, or be affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-20 are pending in the application. Claims 1, 4, 7, 10 and 13-20 are withdrawn from consideration.

This is an appeal from the Examiner's rejection of claims 2-3, 5-6, 8-9 and 11-12 under 35 U.S.C. § 103(a).

IV. STATUS OF AMENDMENTS

The Amendment submitted on February 1, 2006, is the last response submitted with amendments to the claims of the application. The Amendment filed on February 1, 2006 was entered. There are no outstanding amendments to the claims or to the specification in the present application.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention relates to an assay method for detecting a receptor or a ligand by the utilization of a biochemical analysis unit provided with porous adsorptive regions and to a biochemical analysis apparatus for carrying out the assay method. *See* page 1, lines 6-11.

The primary object of the present invention is to provide an assay method using a biochemical analysis unit, wherein problems are capable of being prevented from occurring in that, in cases where a reaction liquid is forcibly circulated through the interior of each of adsorptive regions of the biochemical analysis unit, a signal-to-noise ratio becomes low, and the signal-to-noise varies for different positions of the adsorptive regions. *See* page 6, lines 16-23. Another object of the present invention is to provide a biochemical analysis apparatus for carrying out the assay method using a biochemical analysis unit. *See* page 6, line 24 to page 7, line 1.

The present invention provides an assay method using a biochemical analysis unit, comprising the steps of: i) obtaining a biochemical analysis unit provided with a plurality of porous adsorptive regions, to which ligands or receptors have been bound respectively, and ii) performing a specific binding detecting process comprising the steps of: a) forcibly causing a receptor or a ligand to flow such that the receptor or the ligand flows across each of the porous adsorptive regions of the biochemical analysis unit, the receptor or the ligand being thus subjected to specific binding with the ligands or the receptors, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, the receptor or the ligand being thereby specifically bound to at least one of the ligands, each of which has been bound to

one of the porous adsorptive regions of the biochemical analysis unit, or at least one of the receptors, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, and b) detecting the receptor or the ligand, which has thus been specifically bound to at least one of the ligands or at least one of the receptors, by the utilization of a labeling substance, a liquid being forcibly caused to flow, such that the liquid flows across each of the porous adsorptive regions of the biochemical analysis unit, during the specific binding detecting process, wherein bubble removing processing for removing bubbles, which are present in the liquid, from the liquid is performed during the flowing of the liquid. *see* page 8, line 16 to page 9, line 22. In this assay method, a liquid, which has been subjected to the gas content decreasing processing for decreasing the content of the dissolved gas, may be employed as the liquid, which is forcibly caused to flow. *See* page 9, line 23 to page 10, line 2.

The present invention further provides an assay method using a biochemical analysis unit, comprising the steps of: i) obtaining a biochemical analysis unit provided with a plurality of porous adsorptive regions, to which ligands or receptors have been bound respectively, and ii) performing a specific binding detecting process comprising the steps of: a) forcibly causing a receptor or a ligand to flow such that the receptor or the ligand flows across each of the porous adsorptive regions of the biochemical analysis unit, the receptor or the ligand being thus subjected to specific binding with the ligands or the receptors, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, the receptor or the ligand being thereby specifically bound to at least one of the ligands, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, or at least one of the receptors, each of which has been bound to one of the porous adsorptive regions of the

biochemical analysis unit, and b) detecting the receptor or the ligand, which has thus been specifically bound to at least one of the ligands or at least one of the receptors, by the utilization of a labeling substance, a liquid being forcibly caused to flow, such that the liquid flows across each of the porous adsorptive regions of the biochemical analysis unit, during the specific binding detecting process, wherein bubble dissolving processing for dissolving bubbles, which are present in the liquid, is performed during the flowing of the liquid. *see* page 10, line 3 to page 11, line 8. In this assay method, a liquid, which has been subjected to the gas content decreasing processing for decreasing the content of the dissolved gas, may be employed as the liquid, which is forcibly caused to flow. *See* page 11, lines 9-13.

The above assay methods using a biochemical analysis unit in accordance with the present invention may be modified such that the specific binding detecting process comprises the steps of: a) forcibly causing a reaction liquid containing a labeled receptor or a labeled ligand, which has been labeled with a labeling substance, to flow such that the reaction liquid flows across each of the porous adsorptive regions of the biochemical analysis unit provided with the plurality of the porous adsorptive regions, to which the ligands or the receptors have been bound respectively, the labeled receptor or the labeled ligand being thus subjected to the specific binding with the ligands or the receptors, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, the labeled receptor or the labeled ligand being thereby specifically bound to at least one of the ligands, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, or at least one of the receptors, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, and b) detecting the labeled receptor or the labeled ligand, which

has thus been specifically bound to at least one of the ligands or at least one of the receptors, by the utilization of the labeling substance. *See* page 11, line 14 to page 12, line 12.

Also, the aboveassay methods using a biochemical analysis unit in accordance with the present invention may be modified such that the specific binding detecting process comprises the steps of: a) subjecting the receptor or the ligand to the specific binding with the ligands or the receptors, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, the receptor or the ligand being thereby specifically bound to at least one of the ligands, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, or at least one of the receptors, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, b) forcibly causing a reaction liquid containing a labeled body, which has been labeled with a labeling substance, to flow such that the reaction liquid flows across each of the porous adsorptive regions of the biochemical analysis unit, the labeled body being thus specifically bound to the receptor or the ligand having been specifically bound to at least one of the ligands, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, or at least one of the receptors, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, and c) detecting the receptor or the ligand, which has been specifically bound to at least one of the ligands or at least one of the receptors, by the utilization of the labeled body. *See* page 12, line 13 to page 13, line 15.

Further, the above assay methods using a biochemical analysis unit in accordance with the present invention may be modified such that the specific binding detecting process comprises the steps of: a) subjecting an auxiliary substance-bound receptor or an auxiliary

substance-bound ligand, to which an auxiliary substance has been bound, to the specific binding with the ligands or the receptors, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, the auxiliary substance-bound receptor or the auxiliary substance-bound ligand being thereby specifically bound to at least one of the ligands, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, or at least one of the receptors, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, b) forcibly causing a reaction liquid containing a labeling substance, which is capable of undergoing specific binding with the auxiliary substance, to flow such that the reaction liquid flows across each of the porous adsorptive regions of the biochemical analysis unit, the labeling substance, which is capable of undergoing specific binding with the auxiliary substance, being thus specifically bound to the auxiliary substance-bound receptor or the auxiliary substance-bound ligand having been specifically bound to at least one of the ligands, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, or at least one of the receptors, each of which has been bound to one of the porous adsorptive regions of the biochemical analysis unit, and c) detecting the auxiliary substance-bound receptor or the auxiliary substance-bound ligand, which has been specifically bound to at least one of the ligands or at least one of the receptors, by the utilization of the labeling substance. *See* page 13, line 16 to page 14, line 25.

With the above assay method using a biochemical analysis unit in accordance with the present invention, wherein the bubble removing processing for removing the bubbles, which are present in the liquid, from the liquid is performed during the flowing of the liquid, the same

effects as those described above are capable of being obtained. *See* page 18, lines 11-16. Also, with the third assay method using a biochemical analysis unit in accordance with the present invention, wherein the bubble dissolving processing for dissolving the bubbles, which are present in the liquid, is performed during the flowing of the liquid, the same effects as those described above are capable of being obtained. *See* page 19, lines 16-21.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issue on appeal is whether the Examiner improperly finally rejected claims 2-3, 5-6, 8-9 and 11-12 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hess et al. (US 6,716,629) in view of Clark et al. (US 5,358,691).

VII. ARGUMENT

Claims 2-3, 5-6, 8-9, and 11-12 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hess et al (US 6,716,629 B2) in view of Clark et al (US 5,358,691).

A *prima facie* showing of obviousness requires (1) a suggestion or motivation in the references or in the knowledge of one of ordinary skill in the art, to modify the references or to combine reference teachings; (2) a reasonable expectation of success; and (3) a teaching or suggestion of all claimed limitations. For the reasons below, it is respectfully submitted that Hess and Clark do not teach or suggest the subject matter of claims 2 or 3 (or the claims depending therefrom) as required under §103.

The process in claim 2 is directed to an assay method using a biochemical analysis unit, comprising the steps of:

i) obtaining a biochemical analysis unit provided with a plurality of porous adsorptive regions, to which ligands or receptors have been bound respectively, said porous adsorptive regions comprising holes, filled with a porous material, provided in a base plate, and

ii) performing a specific binding detecting process comprising the steps of:

a) forcibly causing a receptor or a ligand to flow such that the receptor or the ligand flows through each of the holes of the biochemical analysis unit, the receptor or the ligand being thus subjected to specific binding with the bound ligands or the bound receptors, the receptor or the ligand being thereby specifically bound to at least one of the bound ligands, or to at least one of the bound receptors, and

b) detecting the receptor or the ligand, which has thus been specifically bound

to at least one of the bound ligands or at least one of the bound receptors, by the utilization of a labeling substance,

a liquid being forcibly caused to flow, such that the liquid flows through each of the holes of the biochemical analysis unit, during the specific binding detecting process,

wherein bubble removing processing for removing bubbles, which are present in the liquid, from the liquid is performed during the flowing of the liquid.

The process of claim 3 is directed to an assay method using a biochemical analysis unit, comprising the steps of:

i) obtaining a biochemical analysis unit provided with a plurality of porous adsorptive regions, to which ligands or receptors have been bound respectively, said porous adsorptive regions comprising holes, filled with a porous material, provided in a base plate, and

ii) performing a specific binding detecting process comprising the steps of:

a) forcibly causing a receptor or a ligand to flow such that the receptor or the ligand flows through each of the holes of the biochemical analysis unit, the receptor or the ligand being thus subjected to specific binding with the bound ligands or the bound receptors, the receptor or the ligand being thereby specifically bound to at least one of the bound ligands, or to at least one of the bound receptors, and

b) detecting the receptor or the ligand, which has thus been specifically bound to at least one of the bound ligands or at least one of the bound receptors, by the utilization of a labeling substance,

a liquid being forcibly caused to flow, such that the liquid flows through each of the holes of the biochemical analysis unit, during the specific binding detecting process,

wherein bubble dissolving processing for dissolving bubbles, which are present in the liquid, is performed during the flowing of the liquid.

Accordingly, claim 2 recites a bubble removing processing for removing bubbles, which are present in the liquid, from the liquid is performed during the flowing of the liquid, and claim 3 recites a bubble dissolving processing for dissolving bubbles, which are present in the liquid, is performed during the flowing of the liquid.

The Examiner cites Hess as disclosing the claimed processes, except for the step of performing a bubble removing or dissolving process during the flowing of the liquid, and cites Clark as teaching a step of automatically flushing bubbles out of a fluidics system in order to prevent the presence of air bubbles from affecting the precision and accuracy of the dispenser. The Examiner asserts that the motivation to combine the references is to provide the advantages of a more precise and accurate dispensation by removing bubbles from a fluidic system.

It is respectfully submitted that there is no motivation to combine Hess and Clark. Clark specifically discloses that the problem is associated with a syringe and discloses, at column 21, lines 7-19, that (emphasis added):

> Various elements of syringe 122 which provides automatic bubble flushing and fluids to the various piperting mechanisms is provided in various views in FIGS. 9, 9A and 9B. The ability of diagnostic instrumentation to accurately perform an assay is ***critically dependent on the precision and accuracy with which syringes, i.e. pipetting, can aspirate and dispense reagents and samples***. The precision and accuracy of a syringe is severely degraded by the presence of small air bubbles inside a syringe. Bubbles, unfortunately, are all too common and are difficult to remove or avoid. Syringe 122 avoids these problems by automatically flushing bubbles completely out of the fluidics system.

More importantly, Clark discloses "various elements of a syringe 122 which provides automatic

bubble flushing" shown in Figures 9, 9A and 9B and various structures at column 21, lines 19-48, and discloses that "the precision and accuracy of a syringe is severely degraded by the presence of small air bubbles inside a syringe". Therefore, Clark discloses problems associated with the use of a syringe and modifications to a syringe that automatically remove bubbles formed in the syringe. In this regard, it is submitted that the entire disclosure of a reference must be considered.

In contrast to Clark, Hess discloses that "[t]he array can also be loaded by applying a pressure across the platen, thereby causing a dilute solution of reagent and/or sample to flow through the array of through-holes". *See* col. 28, lines 16-19 (underlining added). This disclosure does not relate to the use of a syringe, and relates to the application of pressure across the platen. In addition, Hess does not disclose that there are problems with bubble formation when pressure is applied across the platen.

The Examiner takes the position that the absence of such disclosure does not mean that there are no problems of bubble formation. However, without any teaching of a problem associated with pressure loading, the Examiner has not provided a basis or explanation for why one of ordinary skill in the art would modify the process of Hess.

For at least the above reasons, one of ordinary skill in the art would not look to Clark to modify Hess, particularly since Hess does not disclose any problems of bubble formation caused by pressure loading and Clark specifically addresses problems specifically associated with a syringe, i.e., bubble formation in a syringe during, for example, pipetting.

Furthermore, there is no reasonable expectation of success. The Examiner asserts that while Hess does not explicitly describe bubble formation, it does not follow that Hess' system

would not have problems with bubbles and that Clark's bubble-removal process would not work with Hess' system.

However, Hess discloses applying pressure across a platen and not to the use of a syringe. The Examiner fails to explain why or how Clark's bubble-removal process would work in Hess' system. Specifically, Clark discloses, at column 21, lines 32-48, that:

> While the crossflow is occurring, the piston 124 is reciprocated inside the bore 128. This reciprocation causes high fluid flow velocities in the annulus 138 between the piston 124 and the bore 128. The high flow velocity dislodges any bubbles that may be adhering to the piston 124 or bore wall. The inward stroke of the piston 124 pushes these dislodged bubbles across the crossflow area where they are swept out of the syringe. The piston end 132 and the bore end 130 have similar spherical shapes. When the piston 124 strokes to its full inward extension, it comes very close to the bore end 130. Any bubble that may be stuck on the bore end 130 is disrupted and dislodged. Likewise, when the piston strokes to its full outward extension, its end is flush with the seal 126. The sequence of reciprocating the piston while crossflowing can be automatically executed any time by the system.

In the above disclosure, Clark discloses specific elements of the syringe and how it functions to remove the bubbles formed inside the syringe. It is submitted that the structural parts of the syringe that remove the bubbles could not be incorporated into the pressure loading system of Hess. Therefore, contrary to the Examiner's position, one of ordinary skill in the art would not expect that Clark's bubble-removal step could be used in the pressure-loading system of Hess.

For the above reasons, it is respectfully submitted that a *prima facie* case of obviousness has not been established because there is no teaching or suggestion in either reference that would motivate one of ordinary skill in the art to modify the process of Hess based on Clark with a reasonable expectation of success to arrive at the claimed invention.

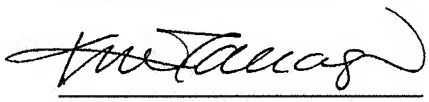
III. Conclusion

In view of the above, Appellants submit that the Examiner's rejection is improper and should be reversed.

The fee required under 37 C.F.R. §41.37(a) and 1.17(c) is charged to Deposit Account No. 19-4880 via EFS payment screen.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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Date: October 26, 2007

CLAIMS APPENDIX

CLAIMS 2-3, 5-6, 8-9 and 11-12 ON APPEAL:

2. An assay method using a biochemical analysis unit, comprising the steps of:

i) obtaining a biochemical analysis unit provided with a plurality of porous adsorptive regions, to which ligands or receptors have been bound respectively, said porous adsorptive regions comprising holes, filled with a porous material, provided in a base plate, and

ii) performing a specific binding detecting process comprising the steps of:

a) forcibly causing a receptor or a ligand to flow such that the receptor or the ligand flows through each of the holes of the biochemical analysis unit, the receptor or the ligand being thus subjected to specific binding with the bound ligands or the bound receptors, the receptor or the ligand being thereby specifically bound to at least one of the bound ligands, or to at least one of the bound receptors, and

b) detecting the receptor or the ligand, which has thus been specifically bound to at least one of the bound ligands or at least one of the bound receptors, by the utilization of a labeling substance,

a liquid being forcibly caused to flow, such that the liquid flows through each of the holes of the biochemical analysis unit, during the specific binding detecting process,

wherein bubble removing processing for removing bubbles, which are present in the liquid, from the liquid is performed during the flowing of the liquid.

3. An assay method using a biochemical analysis unit, comprising the steps of:

i) obtaining a biochemical analysis unit provided with a plurality of porous adsorptive

regions, to which ligands or receptors have been bound respectively, said porous adsorptive regions comprising holes, filled with a porous material, provided in a base plate, and

ii) performing a specific binding detecting process comprising the steps of:

a) forcibly causing a receptor or a ligand to flow such that the receptor or the ligand flows through each of the holes of the biochemical analysis unit, the receptor or the ligand being thus subjected to specific binding with the bound ligands or the bound receptors, the receptor or the ligand being thereby specifically bound to at least one of the bound ligands, or to at least one of the bound receptors, and

b) detecting the receptor or the ligand, which has thus been specifically bound to at least one of the bound ligands or at least one of the bound receptors, by the utilization of a labeling substance,

a liquid being forcibly caused to flow, such that the liquid flows through each of the holes of the biochemical analysis unit, during the specific binding detecting process,

wherein bubble dissolving processing for dissolving bubbles, which are present in the liquid, is performed during the flowing of the liquid.

5. A method as defined in Claim 2 wherein the specific binding detecting process comprises the steps of:

a) forcibly causing a reaction liquid containing a labeled receptor or a labeled ligand, which has been labeled with a labeling substance, to flow such that the reaction liquid flows through each of the holes of the biochemical analysis unit provided with the plurality of the porous adsorptive regions, to which the bound ligands or the bound receptors have been

bound respectively, the labeled receptor or the labeled ligand being thus subjected to the specific binding with the bound ligands or the bound receptors, the labeled receptor or the labeled ligand being thereby specifically bound to at least one of the bound ligands, or to at least one of the bound receptors, and

b) detecting the labeled receptor or the labeled ligand, which has thus been specifically bound to at least one of the bound ligands or at least one of the bound receptors, by the utilization of the labeling substance.

6. A method as defined in Claim 3 wherein the specific binding detecting process comprises the steps of:

a) forcibly causing a reaction liquid containing a labeled receptor or a labeled ligand, which has been labeled with a labeling substance, to flow such that the reaction liquid flows through each of the holes of the biochemical analysis unit provided with the plurality of the porous adsorptive regions, to which the bound ligands or the bound receptors have been bound respectively, the labeled receptor or the labeled ligand being thus subjected to the specific binding with the bound ligands or the bound receptors, the labeled receptor or the labeled ligand being thereby specifically bound to at least one of the bound ligands, or to at least one of the bound receptors, and

b) detecting the labeled receptor or the labeled ligand, which has thus been specifically bound to at least one of the bound ligands or at least one of the bound receptors, by the utilization of the labeling substance.

8. A method as defined in Claim 2 wherein the specific binding detecting process comprises the steps of:

a) subjecting the receptor or the ligand to the specific binding with the bound ligands or the bound receptors, the receptor or the ligand being thereby specifically bound to at least one of the bound ligands, or to at least one of the bound receptors,

b) forcibly causing a reaction liquid containing a labeled body, which has been labeled with a labeling substance, to flow such that the reaction liquid flows through each of the holes of the biochemical analysis unit, the labeled body being thus specifically bound to the receptor or the ligand having been specifically bound to at least one of the bound ligands, or to at least one of the bound receptors, and

c) detecting the receptor or the ligand, which has been specifically bound to at least one of the bound ligands or at least one of the bound receptors, by the utilization of the labeled body.

9. A method as defined in Claim 3 wherein the specific binding detecting process comprises the steps of:

a) subjecting the receptor or the ligand to the specific binding with the bound ligands or the bound receptors, the receptor or the ligand being thereby specifically bound to at least one of the bound ligands, or to at least one of the bound receptors,

b) forcibly causing a reaction liquid containing a labeled body, which has been labeled with a labeling substance, to flow such that the reaction liquid flows through each of the holes of the biochemical analysis unit, the labeled body being thus specifically bound to the receptor

or the ligand having been specifically bound to at least one of the bound ligands, or to at least one of the bound receptors, and

c) detecting the receptor or the ligand, which has been specifically bound to at least one of the bound ligands or at least one of the bound receptors, by the utilization of the labeled body.

11. A method as defined in Claim 2 wherein the specific binding detecting process comprises the steps of:

a) subjecting an auxiliary substance-bound receptor or an auxiliary substance-bound ligand to the specific binding with the bound ligands or the bound receptors, the auxiliary substance-bound receptor or the auxiliary substance-bound ligand being thereby specifically bound to at least one of the bound ligands, or to at least one of the bound receptors,

b) forcibly causing a reaction liquid containing a labeling substance, which is capable of undergoing specific binding with the auxiliary substance, to flow such that the reaction liquid flows through each of the holes of the biochemical analysis unit, the labeling substance, which is capable of undergoing specific binding with the auxiliary substance, being thus specifically bound to the auxiliary substance-bound receptor or the auxiliary substance-bound ligand having been specifically bound to at least one of the bound ligands, or to at least one of the bound receptors, and

c) detecting the auxiliary substance-bound receptor or the auxiliary substance-bound ligand, which has been specifically bound to at least one of the bound ligands or at least one of the bound receptors, by the utilization of the labeling substance.

12. A method as defined in Claim 3 wherein the specific binding detecting process comprises the steps of:

a) subjecting an auxiliary substance-bound receptor or an auxiliary substance-bound ligand to the specific binding with the bound ligands or the bound receptors, the auxiliary substance-bound receptor or the auxiliary substance-bound ligand being thereby specifically bound to at least one of the bound ligands, or to at least one of the bound receptors,

b) forcibly causing a reaction liquid containing a labeling substance, which is capable of undergoing specific binding with the auxiliary substance, to flow such that the reaction liquid flows through each of the holes of the biochemical analysis unit, the labeling substance, which is capable of undergoing specific binding with the auxiliary substance, being thus specifically bound to the auxiliary substance-bound receptor or the auxiliary substance-bound ligand having been specifically bound to at least one of the bound ligands, or to at least one of the bound receptors, and

c) detecting the auxiliary substance-bound receptor or the auxiliary substance-bound ligand, which has been specifically bound to at least one of the bound ligands or at least one of the bound receptors, by the utilization of the labeling substance.

EVIDENCE APPENDIX:

Pursuant to 37 C.F.R. § 41.37(c)(1)(ix), submitted herewith are copies of any evidence submitted pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132 or any other evidence entered by the Examiner and relied upon by Appellant in the appeal.

None.

RELATED PROCEEDINGS APPENDIX

Submitted herewith are copies of decisions rendered by a court or the Board in any proceeding identified about in Section II pursuant to 37 C.F.R. § 41.37(c)(1)(ii).

None.

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Kenji NAKAJIMA

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Examiner: Leon Yun Bon LUM

Filed: October 24, 2003

For: ASSAY METHOD USING A BIOCHEMICAL ANALYSIS UNIT AND BIOCHEMICAL ANALYSIS APPARATUS

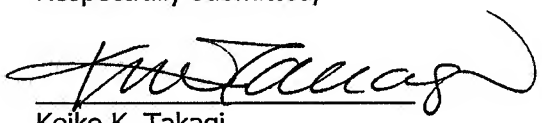
SUBMISSION OF APPEAL BRIEF

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an Appeal Brief. The statutory fee of $510.00 is charged to Deposit Account No. 19-4880 via EFS payment screen. The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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